

REMARKS

With this amendment, claims 56, 63, and 72 have been amended, claims 59-61 have been canceled and claims 73-75 are newly added. Accordingly, claims 56-58 and 62-75 are presented for consideration by the Examiner. Applicants further note that the rejection of claims 57, 66, and 67 under 35 USC §112, ¶1 for non-enablement has been withdrawn. With this Amendment, the rejection of claims 59-61 under 35 USC §112, ¶1, is moot.

Response to the Rejection of Claims 57-61, 66-67, and 72 Under 35 USC §112, ¶1

In the most recent Office Action, the Examiner has again rejected claims 57-61, 66, and 67 under 35 USC §112, ¶1 as failing to comply with the written description requirement. Applicants note that dependent claims 57-58 and 66-67 depend directly or indirectly from independent claim 56 which has not been rejected on this ground.

Specifically, the Examiner has asserted, page 6, that applicants are claiming subject matter "which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) ...had possession of the claimed invention." Applicants do not understand the rejection to be that statements found in the specification are not commensurate in scope with the claimed subject matter. In fact, statements found in the specification do provide notice that applicants were in possession of the subject matter being claimed. The Examiner opines that (page 7) the specification "provides no criteria" for selection of proteins or enzymes that have the requisite properties "without extensive experimentation." While "undue experimentation" is a factor relevant to a rejection based on lack of enablement, applicants note that the lack of enablement rejection has been dropped for claims 57, 66, and 67.

Applicants have provided an extensive listing of known proteins and enzymes which are suitable for controlled release from the silicone matrix when used to practice the methods of the claimed invention. Applicants need not explain to those skilled in the art what they already know. Specifically, Claim 57 recites that the active agent is selected such that it removes necrotic tissues and claim 58 recites that the active agent cleanses the wound. Claims 66-67 also recite that the active agent is selected such that it removes necrotic tissues. Applicants have provided several examples in their specification of the removal/debridement of eschar (defined

as necrotic tissue). See, Examples 11-15 and the enzymes described at pages 13-14 of the specification. Thus, contrary to the Examiner's assertions, applicants have provided both examples and guidance for selecting active agents.

The rejections of claims 59-61 is now moot. With respect to claim 72, that claim has now been amended to recite that the active agent is a protease enzyme and that the second active agent is a protease enzyme inhibitor. Again, applicants have provided several examples of suitable active agents that remove necrotic tissue and have also provided several examples of suitable inhibitors at page 20, lines 1-7.

The rejected claims are specific to methods of treating wounded tissue removal, not the use of any enzyme for any purpose. Applicants have described a topical preparation which is useful to contain and then release the enzymatic or protein active agents when the preparation is topically applied. Applicants have also provided several examples, as discussed in detail above, which provide guidance in the selection of such enzyme and protein active agents for the specific use recited in these claims. Contrary to the Examiner's assertions, the present situation is not at all like the situation in *Univ. of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424. Here, specific enzymes have been identified, and working examples have been provided, evidencing the activity of such enzymes in the treatment of wounded tissue. In *Univ. of Rochester*, the patentee failed to identify a single specific compound that selectively inhibited PGHS-2.

Response to the Rejection of Claims 56, 62-65, and 68-71 under 35 USC §103

Also in the Office Action, the Examiner rejected claims 56, 62-65, and 68-71 under 35 USC §103 as unpatentable over Powell et al (US 6060546). Powell is directed to non-aqueous silicone emulsions.

Independent claim 56 has been amended to recite that the internal phase includes a hydrophilic component containing water. Basis for this amendment is found in the specification, for example, at page 9, lines 2-10. Because Powell is directed to a non-aqueous emulsion, Powell does not teach or suggest an internal phase that includes at least one hydrophilic component containing water. Nor, with respect to claim 71, does Powell teach or suggest a composition that contains LG12 enzyme. Accordingly, the rejection should be withdrawn.

Newly added claims 73-75 are directed to methods that utilize the enzyme LG12. Powell does not teach or suggest such a method. Accordingly, newly-added claims 73-75 are also believed to be patentable

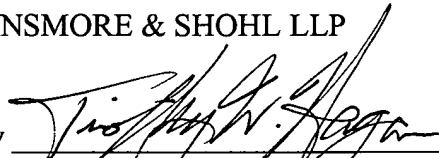
Conclusion

For all of the above reasons, applicants submit that claims 56-58 and 62-72, as amended, and newly added claims 73-75 are patentable over the cited and applied prior art and are in compliance with §112. Early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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